

REMARKS/ARGUMENTS

Claims 1-3, 6-10 and 12-13 are pending in the instant application. Favorable reconsideration of the present claims is kindly requested.

Rejection under 35 U.S.C. § 112

Claims 1-3, 7-10 and 12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action alleges that the Application does not disclose a non-split membrane. Applicant respectfully traverses the rejection, for at least the following reasons.

Applicant gratefully acknowledges the withdrawal of the rejection of claim 13 on the same grounds made in the previous Office Action mailed July 20, 2009. Reiterating Applicant's comments on that rejection, equally applicable here, the test for sufficient written description is not an *ipsis verbis* test. *Martin v. Johnson*, 454 F.2d 746, 172 U.S.P.Q. 391 (CCPA 1972); M.P.E.P. § 2163(II)(A)(3)(a). The specification need only "describe the claimed invention so that one skilled in the art can recognize what is claimed." *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004). Moreover, the drawings themselves form part of the written description. "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, **figures, diagrams**, and formulas that fully set forth the claimed invention." M.P.E.P. § 2163(I) (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997))(emphasis added).

In this case, Applicant refers to Figs. 2a and 3 as originally filed. Membrane 17 is depicted in cross-section as a solid unit, *i.e.*, non-split. Drawing convention among those skilled in the art would be to depict any such pre-existing split. For example, and in contrast to Applicant's instant disclosure, the Wyatt reference clearly depicts the preexisting split in its views (e.g., cross-sectional views, Figs. 6, 7). The Examiner has acknowledged more than once that Wyatt does not teach a membrane lacking a pre-existing split therethrough.

Moreover, on the merits of the claim, the Office Action has extended the same rationale previously applied to independent claims 1 and 12, which recited a first "non-split membrane", to independent claim 13, which recites a first membrane "lacking any pre-existing opening therethrough". By its own consideration, the Office Action conflates the two features, and does

not acknowledge any patentable distinction between them. However, the former is singled out as allegedly lacking support, while the latter is explicitly acknowledged as proper.

Therefore, Applicant respectfully submits that the application as originally filed includes ample support for a “non-split membrane” as recited in independent claims 1 and 12, and that the rejection is poorly taken.

Notwithstanding the foregoing, and without prejudice or acquiescence in the propriety of the rejection, Applicant gratefully acknowledges the Office Action’s indication that the specification does support a membrane having “no pre-existing openings there through.” (Office Action, p. 4). Therefore, independent claims 1 and 12 are amended above to remove the characterization of the first membrane as “non-split”, and to recited in it place a first membrane –having no pre-existing openings therethrough—. In view of the Office Action’s acknowledgement that this feature of the membrane does not present any new matter, Applicant respectfully submits that the rejection has been obviated, and kindly requests favorable reconsideration and withdrawal.

Rejection under 35 U.S.C. § 103

Claims 1-3, 7-10 and 12-13 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,632,735 to Wyatt, *et al.* (“Wyatt”), in view of U.S. Patent No. 5,685,866 to Lopez (“Lopez”). Applicant respectfully traverses the rejection, for at least the following reasons.

By this rejection, the Office Action extends its previous ground of rejection applied to claims 1-3, 7-10 and 12 to include claim 13. In addition to the above-noted amendments to claims 1 and 12, independent claims 1, 12 and 13 are further amended to recite that the second flexible membrane also have no pre-existing openings therethrough. This amendment is likewise supported by the original specification as filed, and no new matter has been added.

As acknowledged by the Office Action, Wyatt does not disclose a device comprising a membrane with no preexisting openings therethrough. Instead, Wyatt discloses a device comprising a split septum (e.g., ref. 27, Fig. 8A). If a membrane, such as the membrane 36 of the device disclosed by Lopez (e.g., Fig. 3) is held against the split septum of Wyatt's device with a pressure, the split in the split septum may open and it may thereby allow medical substance inside the device to leak out of the device. Such is the nature of a pre-existing opening, and unavoidable where it is used.

The Office Action has stated the opinion that to use a membrane with no preexisting openings therethrough instead of a split membrane is a matter of simple substitution of two known equivalents in the art. Applicant respectfully disagrees. A membrane with no pre-existing openings is not the equivalent of a split membrane in all circumstances.

The membrane of the device according to the present claims is not only used to keep the device sterile, but it is also used to prevent medical substance from leaking out of the device while a medical substance is being injected into the device via the device's membrane. The amended independent claims 1, 12 and 13 are therefore considered to be patentable over Wyatt and/or Lopez, singly or in combination. Even though a split membrane may arguably provide a sufficient seal to maintain a sterile condition in storage (i.e., Lopez), medical substances may leak out of the split in a membrane while a medical substance is being injected through the membrane using a spike element.

Underlying the present claims is Applicant's insight that when injecting a medical substance through a membrane, it is desirable to use an injection component having a second membrane with no pre-existing openings. The second membrane must be held with a pressure against a first membrane with no pre-existing openings therethrough. A needle is pushed through both membranes to inject a medical substance while the two membranes are pressed together and then retracted through both membranes after the medical substance has been injected into the device. Only once the needle has been retracted can the membranes be separated. This injection procedure eliminates the risk of medical substances coming into contact with ambient air during the injection of a medical substance into an injection device.

As recited in independent claims 1, 12 and 13, the two membranes are held together with a pressure during the injection of medical substance. One of ordinary skill in the art would be motivated away from using a split membrane/split membranes since putting pressure on a split membrane may cause the split to open, whereby the risk of leakage of medical substances into breathable air would not be eliminated. This drawback of a pre-perforated or split membrane would be obvious to a skilled person considering all the recited features and conditions of the present claims, i.e., once he/she has knowledge of the claimed invention by Applicant's instant disclosure. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). However, it would not be

obvious to a skilled person who, absent Applicants instant disclosure, seeks a membrane only to preserve the sterile state of the spike 24 according to Lopez. Therefore, the Examiner's assertion (Office Action, p. 3) that that a split membrane is the equivalent of a membrane with no pre-existing openings, if applicable within the disclosure of Lopez, does not carry over to the proposed combination of Lopez with Wyatt, nor to the express language of Applicant's instant claims.

The only remaining rationale supporting the purported rejection of the instant claims appears to be the improper hindsight application of Applicant's own teachings. An obviousness rejection based solely upon hindsight reconstruction remains impermissible. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007).

Furthermore, Applicant respectfully submits that the explicit prejudice to reject the claims without regard to their subject matter or that of the cited references is improper. "The examiner still finds that after six office actions on the merits (this being the seventh) there is no allowable subject matter in the claims or the specification in general." (Office Action, p. 4) However, the earliest rejections based upon Schock, *et al.* (U.S. Pat. No. 5,254,097) have since been withdrawn as overcome by subsequent prosecution. Moreover, the Examiner had expressed the opinion that a membrane having no pre-existing openings therethrough was not supported by applicant's disclosure (Office Action mailed July 20, 2009), and that Applicant's figures disclosed the air- and liquid-proof membrane was formed of mesh (Telephone Interview held October 23, 2009; Applicants summary thereof filed October 23, 2009). Both these opinions have been clarified as inaccurate in view of subsequent prosecution. Applicant respectfully requests that Examiner hold out the possibility that the ultimate judgement of obviousness is similarly mistaken, in view of the foregoing.

Therefore, independent claims 1, 12 and 13 as amended are respectfully submitted as patentably distinguished over Wyatt and/or Lopez, taken singly or in combination. Claims 2-3 and 7-10 each depend, directly or indirectly, from independent claim 1. These dependent claims are each separately patentable, but in the interest of brevity they are offered as patentable for at least the same reasons as their underlying independent base claim, the feature of which are incorporated by reference. Therefore, Applicant respectfully submits that the rejection have been obviated, and kindly requests favorable reconsideration and withdrawal.

Conclusion

In light of the foregoing, Applicant respectfully submits that all claims are patentable, and further that the instant application is in condition for allowance. An early and favorable Notice of Allowability is kindly solicited.

THIS CORRESPONDENCE IS BEING
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RCF/DJT:lf

Respectfully submitted,



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